Appendix 4 – 510(k) Summary

510(k) Summary of Safety and Effectiveness

SEP 2 3 2011

Submitter's information

Topera, Inc.
Contact: Ruchir Sehra, MD
Phone: 858 367-3395
03/22/2011

Device/ classification name

Device Name:
- RhythmView Workstation

Classification/Common name:
- Programmable diagnostic computer

The marketed device(s) to which substantial equivalence is claimed:
- Astronomer + (K003362)
- CARTO XP Mapping System (K013083)

Device description

The RhythmView is comprised of these major components,

1. RhythmView hardware – Computer, monitor, keyboard, and mouse
2. RhythmView Software – Software pre-installed

The RhythmView Workstation takes electrical signals collected from multi-polar electrophysiology catheters and outputs a graphic display that assists in the diagnosis of cardiac arrhythmias.

Indications for use

The RhythmView™ Workstation is a computerized system that assists in the diagnosis of complex cardiac arrhythmias. The RhythmView™ Workstation is used to analyze electrogram and electrocardiogram signals and display them in a visual format.

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510(k) Summary of Safety and Effectiveness, Continued

Technological characteristics

The table below lists the technological characteristics for both the new and predicate devices

Device Characteristic	New Device RhythmView™	Predicate Device Astronomer +	Predicate Device CARTO XP
Signal capture	No	Yes	Yes
Signal processing	Yes	Yes	Yes
Location capability	No	Yes	Yes
Post processing display - propagation map	Yes	No	Yes
Grid display of electrode signals	Yes	Yes	No

Performance data

The RhythmView System underwent extensive bench testing, including a wide variety of cardiac electrogram data, to demonstrate that it was as safe and as effective as the predicate devices.

The RhythmView System passed all verification and validation tests in accordance with predetermined specifications and appropriate test criteria. There were no new questions of safety and effectiveness raised.

Conclusion

Verification and validation testing were conducted to establish the performance characteristics of the RhythmView System. The results demonstrate that the RhythmView is safe and effective when used in accordance with its intended use and labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -W066-G609
Silver Spring, MD 20993-0002

Topera, Inc.
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SEP 23 2011

Re: K110878
Trade/Device Name: RhythmView
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: September 8, 2011
Received: September 12, 2011

Dear Dr. Sehra:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Appendix 3 – Indications for Use

Indications for Use Statement

Statement

The Indications for Use Statement:

510(k) Number: K110878

Device Name: RhythmView Workstation

The RhythmView™ Workstation is a computerized system that assists in the diagnosis of complex cardiac arrhythmias. The RhythmView™ Workstation is used to analyze electrogram and electrocardiogram signals and display them in a visual format.

Prescription Use __X__ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K110878